DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 9, 2015

Beijing Allgens Medical Science & Technology Company, Ltd
Helen Cui, Ph.D.
Director of RA/QA
7 Liberty Ridge Road
Basking Ridge, New Jersey 07920

Re: K141725
Trade/Device Name: Bongold™ Bone Graft Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 1, 2015
Received: June 5, 2015

Dear Dr. Cui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141725

Device Name
Bongold™ Bone Graft Material

Indications for Use *(Describe)*
Bongold is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the pelvis and extremities. Bongold must be used with autograft as a bone graft extender in the extremities. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Bongold resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Chapter 5: 510(k) Summary

June 30, 2015

Applicant Name and Address: Beijing Allgens Medical Science & Technology Co., Ltd
Beijing BDA IPE Building #2, Disheng Donglu #1
Beijing, 100176
China

Contact Person: Helen Cui, Ph.D., Director of RA/QA, CTO
Tel: (908) 3924742
Fax: 732.453.3862

Date of Summary: March 20, 2015
Device Common Name: Bone Void Filler
Device Trade Name: Bongold ™ Bone Graft Material
Device Classification Name: Filler, Bone Void, Calcium Compound
Regulation Number: 888.3045
Product Code: MQV
Device Class: Class II
Predicate Device(s):

- HEALOS® Bone Graft Material (K012751) (Primary predicate)
- OssiMend ™ Bone Graft Material (K052812) (Reference predicate)
- MASTERGRAFT® Strip(K082166) (Reference predicate)
- Vitoss® Scaffold Foam Bone Graft Material (K032288) (Reference predicate)

Description of the Device

Bongold™ Bone Graft Material is a composite of synthetic hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$] and type I collagen. The composite material is a resorbable, porous, osteoconductive bone graft matrix. It is available as a lyophilized matrix in particle forms, cylinders and blocks. This bone graft material contains approximately 45% mineral by weight. Bongold™ device is intended to be used as bone void filler for voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e., the pelvis, and/or extremities).

Bongold™ cylinders and blocks can be cut into shapes and are designed to retain their shape and physical integrity following implantation into a bony site, while the particle form can be packed to fit the bone defect. The product is sterile and for single use only.

Intended Use

Bongold™ is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the pelvis and extremities. Bongold™ must be used with autograft as a bone graft

extender in the extremities. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Bongold resorbs and is replaced with bone during the healing process.

510(k) Summary of Safety and Effectiveness

Summary/Comparison of Technological Characteristics

(a) Technological Characteristics

Bongold ™ Bone Graft Material and its predicates have the same key technological characteristics. In particular, Bone Graft Material and its predicates are the same with respect to intended use, design, materials, material characterization, and product forms.

Bongold ™ Bone Graft Material and its predicates are designed as 3-dimensional, resorbable, porous, osteoconductive matrices intended to fill voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. The materials used are a combination of previously cleared and commercially marketed calcium phosphate mineral and type I collagen. The product was characterized by physical and chemical bench tests comparing its characteristics to those of the predicate devices. Such tests included mineral structure and content analysis, physical structure analysis, porosity and pore size analysis. Bongold ™ Bone Graft Material has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

(b) Performance Data

Performance studies supporting the product were bone repair studies in a cancellous bone defect model in rabbit.

The device was compared to autograft in animal performance testing in order to demonstrate substantial equivalence to the predicate. Endpoint measurements included radiographs and histology at 4, 8 and 12 weeks. These studies demonstrated with respect to predicate device the safety and performance of the Bongold ™ Bone Graft Material in supporting bone growth in orthopedic applications.

(c) Conclusions Drawn from Nonclinical Tests

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, and animal performance studies show that the Bongold™ Bone Graft Material is safe with respect to predicate device and substantially equivalent to its predicate device.